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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,499	04/12/2000	ALAN FORBES MERRY	1115/0G778	1189

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BERT J LEWEN  
DARBY & DARBY  
805 THIRD AVENUE  
NEW YORK, NY 10022-7513

EXAMINER

BARRETT, THOMAS C

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 10/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/508,499	MERRY, ALAN FORBES
	Examiner Thomas C. Barrett	Art Unit 3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_\_.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-33 and 39-41 is/are pending in the application.

4a) Of the above claim(s) 12-27 and 29-33 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-11,28 and 39-41 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16.

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_

## DETAILED ACTION

### ***Election/Restrictions***

Claim 26 is also withdrawn as requested by the applicant from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, Group II, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

### ***Response to Arguments***

Applicant's arguments filed July 26, 2002 have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e. "such that each **specific** carrier relates to a **specific** site according to their respective codes which **are associated with the substance**...") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The carriers (syringes) are placed in order of use on the tray from left to right. Therefore, the first syringe used correlates to the site that is the farthest left on the tray. In addition, the labels "SHARPS" or "BIOHAZARDS" are codes that associate the site(s) (puncture proof sharps container) with a carrier (used syringe).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 41 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter where "the first and second substance sites **are established** by the predetermined coding of the substance carrier" is not described in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 41 is also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by "established by". In addition, claim 41 recites the limitation "the predetermined coding". There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11, 28, and 39-40 remain rejected under 35 U.S.C. 102(b) as being anticipated by Claeys et al. (4,853,521) as cited in Applicant's IDS. Claeys et al. discloses a method for verifying and administering drugs to a patient, wherein the first and second "coded sites" for a coded carrier (syringe) is determined by its arrangement (by order of use) on the tray (col. 2, lines 61- 63). The first and second "coded sites" do not have to be different "coded sites" because claim 39 claims them to be the same.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11, 28, and 39-41 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Claeys et al. (4,853,521) as cited in Applicant's IDS, in view of University of Maryland (News Article 10). Claeys et al. discloses a method for verifying and administering drugs to a patient, wherein the first "coded site" for a coded carrier (syringe) is determined by its arrangement (by order of use) on the tray (col. 2, lines 61- 63), however fails to disclose a second coded substance site. University of Maryland teaches syringes (carrier) must be placed intact in a puncture proof sharps container that is labeled (a second coded substance site) with the words "SHARPS" or

"BIOHAZARD" which prevents unacceptable risks to staff. Furthermore, the "predetermined coding of the substance carrier" establishes its order of use (and therefore its predetermined substance site) and, considering it is a syringe, establishes that it is placed in a "BIOHAZARD" container. It would have been obvious to one of ordinary skill in the art to combine the teaching of a second coded substance site in the form of a puncture proof sharps container, as taught by University of Maryland, to a method for verifying and administering drugs to a patient as per Claeys et al., in order to prevent unacceptable risks to staff.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

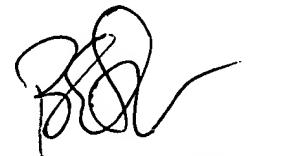
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (703) 308-8295. The examiner can normally be reached Tuesday-Friday between 9:00 A.M. and 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703) 308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3580 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308 0850.



Thomas Barrett  
October 9, 2002



BRUCE SNOW  
PRIMARY EXAMINER